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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and as Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually,
and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

**On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit**

BRIEF OF THE CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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BRIEF OF THE CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

This brief was filed accompanied by written consent of all parties to the case.

INTEREST OF THE *AMICUS CURIAE*

This *amicus curiae* brief is submitted by the Carnegie Commission on Science, Technology, and Government ("the Commission") on the basis of work conducted by its Task Force on Science and Technology in Judicial and Regulatory Decision Making. The Commission, an independent bipartisan body, was established in 1988 by

Carnegie Corporation of New York [1] to assess, and recommend improvements in, the mechanisms by which the federal government and the states incorporate scientific and technological knowledge into policy and decision making. The Commission operates through task forces that address specific issues or organizational entities, and itself sponsors a variety of consultant studies, seminars, and workshops. The membership of the Commission is listed in the Appendix.[2]

Amicus's interest stems from its examination of judicial decision making with regard to science and technology (S&T) issues. A primary conclusion of this three-year study was that a better understanding of scientific methodology would enable the legal system to handle S&T information more effectively.

This brief is not submitted on behalf of either party. Its purpose is to explain the process by which science is conducted and to suggest that the nature of the scientific enterprise requires rejection of current tests for the admissibility of expert testimony. The Commission's approach is intentionally interdisciplinary because it believes that a broader perspective is needed in order to harmonize the interests of science and law so as to achieve improved decision making in our courts.

BACKGROUND

The Nature of the Problem

Recent developments both in law and science have conspired to bring increasingly complex scientific issues before the courts for resolution. In particular, the growth

[1] Carnegie Corporation of New York is a philanthropic foundation created by Andrew Carnegie in 1911 to promote the advancement and diffusion of knowledge and understanding.

[2] No judicial member of the Commission, its Advisory Council or the Task Force on Science and Technology in Judicial and Regulatory Decision Making has participated in any way in the decision to file a brief or in crafting the argument to present to the Court.

in environmental and toxic torts litigation has put enormous pressures on the legal system, which is simultaneously being asked to resolve questions on the cutting edge of science and to develop intricate theories of substantive law. The stress is especially great because these cases involve large numbers of persons and raise profound social, economic and public policy concerns. On the criminal side, DNA testing has brought science of the most sophisticated nature into the courtroom; the research of scientists working at the very frontiers of human knowledge has become relevant in routine criminal cases. The enactment of the Federal Rules of Evidence in 1975 has caused a further problem for the courts as judges have sought to determine the impact of the new rules on handling these new problems.

The district court needs to know its obligation when confronted with an expert who seeks to testify where the scientific evidence is in dispute. Is it the judge's sole responsibility to determine, pursuant to Fed.R.Evid. 702, whether the expert is "qualified" by education and/or experience to be a witness? If that is the only test, critics contend that "junk science" may overwhelm decision making. The "qualified" witness may be a hired gun ready to say anything, or a proponent of fringe theories. On the other hand, allowing a court to screen a "qualified" expert's opinion raises two problems: (1) Is this permissible under the Federal Rules of Evidence? and (2) How can a judge with no specialized scientific training know enough to make preliminary determinations that choose between the contentions of "qualified" experts?

Amicus believes that at this stage in the evolution of law and science, a reanalysis of problems and disaggregation of issues can provide clearer answers to these questions. We think that the Court's grant of certiorari in this case provides an opportune moment for reflection and reformulation.

The Nature of the Scientific Process

Any recasting of the judge's role in the handling of scientific evidence must take account of how science is conducted, and how science can contribute to better decision making in the courts. The essential nature of science has been described as follows:

> In broadest terms, scientists seek a systematic organization of knowledge about the universe and its parts. This knowledge is based on explanatory principles whose verifiable consequences can be tested by independent observers. Science encompasses a large body of evidence collected by repeated observations and experiments. Although its goal is to approach true explanations as closely as possible, its investigators claim no final or permanent explanatory truths. Science changes. It evolves.

National Academy of Sciences, *Science and Creationism: A View from the National Academy of Sciences* 8 (1984) (*"Science and Creationism"*).[3]

Scientists proceed by formulating hypotheses that they then test. "Rigor in the testing of hypotheses is the heart of science." *Id.* at 9. Most scientists agree that the critical task of the scientific community—in testing, refining and systemizing hypotheses—is essential to a convergence toward accurate understanding of the universe and is overlain by sociological perturbations.[4]

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[3] The Committee on Science and Creationism consisted of a distinguished group of six scientists (from four leading universities, the National Institutes of Health and the American Museum of Natural History), three partners in leading law firms, and one Harvard Law School professor, under the direction of James D. Ebert, vice president of the National Academy of Sciences.

[4] Robert Merton, *The Sociology of Science*, 267-78 (1973). Some philosophers and sociologists have gone so far as to assert that scientific "facts" are socially constructed hypotheses that contain value-laden choices. *See* Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 32 Jurimetrics J. 345, 347 (1992) ("Observations [by scientists] achieve the status of 'facts' only if they are produced in accordance with prior agreements about the

The existing body of scientific opinion tends to be conservative, to resist dissent and surprises. This is functional, to allow a firm basis of provisionally corroborated opinion as a stepping-off place for further innovation. These opinions are not always infallible, and some dissent eventually becomes the basis for more far-reaching revisions.

The ongoing scientific endeavor must be viewed as a body of working assumptions, of contingent and sometimes competing scientific claims, likely to be refined even when the core insights are validated with the passage of time and under the glare of pluralistic criticism.[5]

In light of this indeterminacy, how can a judicial system make use of a scientific "fact"? The dynamic nature of the scientific process suggests the impossibility of formulating any legal test of admissibility that requires a court to evaluate the validity of an evolving hypothesis or to choose between competing hypotheses. *Amicus* suggests instead that courts should focus on determining whether the expert engaged in recognized forms of scientific practice in reaching his or her conclusion.

The scientific community uses a variety of markers in evaluating scientific practice—both general markers that extend across fields and specific markers that pertain to a particular discipline. Although appropriate scientific practices cannot be reduced to a single, definitive list, it is possible to suggest the kinds of factors that enter into the analysis. The degree of the scientific claim's accept-

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rightness of particular theories, experimental methods, instrumentation techniques, validation procedures, review processes, and the like. These agreements, in turn, are socially derived through continual negotiation and renegotiation among relevant bodies of scientists.").

[5] Thomas S. Kuhn, *The Structure of Scientific Revolutions* (1970) (suggests that scientific communities adopt "paradigms" that operate as the accepted "disciplinary matrix" until a new paradigm emerges; *id.* at 182; a paradigm "like an accepted judicial decision in the common law . . . is an object for further articulation and specification under new or more stringent conditions." *Id.* at 23.)

ance within a scientific field or discipline reflects the degree to which it has been produced in conformity with the scientific process. Another relevant criterion is the capacity of the claim to withstand criticism, as exemplified by whether a tradition of peer review or other mode of institutionalized self-criticism exists within the field to which the expert belongs. Of central importance is whether the expert adhered to generally recognized forms of scientific inquiry. While different fields utilize somewhat different standards, making it impossible to arrive at a single definition about the nature of scientific practice, and some gray areas of disagreement may exist as to whether the methodology used in testing a particular scientific claim was adequate, some boundary exists beyond which it is no longer possible to consider the claim as having been developed in accordance with recognized scientific practice.

Conventions regarding scientific methodology are analogous to the evidentiary rules that developed in response to our inability to ascertain the objective "truth" of a past historical event. Evidentiary rules seek to curb potential errors in legal fact-finding even though we have little or no empirical evidence that they actually do. The scientific conventions on how research should be done represent the expertise of the scientific community on the best way to ensure that scientific hypotheses conform with a possible state of affairs.

SUMMARY OF ARGUMENT

The core issue in this case is how the federal courts should think about scientific evidence. In the instant case this complex problem is presented in terms of admissibility, raising the issues of whether, when, and to what extent a federal judge may scrutinize an expert's opinion to determine whether it is admissible pursuant to the Federal Rules of Evidence.

This brief takes a somewhat broader view. Because the expertise of the *amicus* centers on the interrelationship between science and law, we discuss more than

admissibility. This brief proposes an integrated approach to scientific evidence that will acknowledge and respect both the special expertise of science and the judge's responsibility to declare the law. It is an attempt to render unto science the concerns of science, and to the law that which lies in the law's domain.

We look first at the judge's task in ruling on the admissibility of evidence, and propose a new set of criteria geared to the process by which scientific hypotheses are developed—criteria that require the court to consider whether the scientific claim on which the expert's opinion rests is the product of a recognized form of scientific inquiry. An opinion that purports to answer a scientific question without having engaged in an appropriate scientific inquiry is incapable of providing a systematic explanation that satisfies our demand for rational proof.

Because judges are increasingly being asked to consider scientific thinking in the context of rulings on the sufficiency of evidence, however, we take the liberty of also exploring the very different questions about scientific evidence that a court may have to examine in that context. We think such an examination completes the picture of the judge's responsibility vis-à-vis scientific evidence, sheds light on the admissibility problem, and helps delineate the respective spheres of scientist and judge.

We strongly urge this Court to go beyond the simplistic "general acceptance" test derived from *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). "General acceptance" is an inadequate vehicle for thinking about science in the courtroom. It fails to provide federal judges with sufficient guidance on how to analyze complex scientific issues because its formula is too vague and misleading, and is incompatible with the essence of the scientific endeavor. The unresponsiveness of "general acceptance" to the scientific process leads to an unprincipled test that taken literally rejects valuable insights that bear all the hallmarks of acceptable science, but provides no guidance on how to distinguish the product of marginal or insupportable fringe activities.

We also argue that making peer review a sole condition for the admissibility of all scientific evidence is ill-advised. Imposition of such a requirement does not reflect the realities of either litigation or the role of science in litigation.

ARGUMENT

I. WHEN RULING ON WHETHER AN EXPERT'S OPINION BASED ON SCIENTIFIC EVIDENCE IS ADMISSIBLE, A COURT SHOULD DETERMINE IF THE UNDERLYING SCIENTIFIC CLAIM WAS THE PRODUCT OF A RECOGNIZED FORM OF SCIENTIFIC INQUIRY.

An expert opinion that is purportedly based on scientific observation is of value in resolving a controverted issue only if it embodies a scientifically plausible mode of reasoning. Separating valid from invalid hypotheses requires that the judge understand science as a process of producing claims about the actual world. It does not require that a judge understand or undertake an extensive examination of the hypotheses being put forth.

A. The Two Current Modes of Analysis

1. *The* Frye *test.*

Prior to the enactment of the Federal Rules of Evidence many federal courts purported to follow the so-called "general acceptance" test that had its genesis in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).[6]

[6] In *Frye*, the court had stated:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. at 1014.

Since the enactment of the Federal Rules, some courts have continued to give allegiance to *Frye*, and one of the questions before this Court is whether *Frye* has survived the advent of the Federal Rules. *Amicus* requests the Court to discard *Frye*, not because a federal court does not have the power to make threshold determinations with regard to the admissibility of scientific evidence,[7] but because "general acceptance" is an ineffective test that misconceives the nature of the scientific enterprise. It assumes that there is much more definiteness in science than actually exists, and that this precision takes the form of widely held beliefs about reality that can readily be found. *See* Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 32 Jurimetrics J. 345 (1992). In fact, scientific claims remain provisional and continue to be challenged until incentives for investigating the problem disappear.[8]

2. *The* Downing *test.*

In *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), the Third Circuit formulated an alternative to the "general acceptance" test. The *Downing* test centers

[7] *See United States v. Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985) ("[W]e can assume that the drafters of the Federal Rules of Evidence were aware that the *Frye* test was a judicial creation, and we find nothing in the language of the rules to suggest a disapproval of such interstitial judicial rulemaking. Therefore, although the codification of the rules of evidence may counsel in favor of a re-examination of the general acceptance standard, on balance we conclude that the Federal Rules of Evidence neither incorporate nor repudiate it.").

[8] *Science and Creationism*, *supra* p. 4 at 10. ("Scientific theories . . . allow us to anticipate yet unknown phenomena and thus to focus research on more narrowly defined areas. If the results of testing agree with predictions from the theory, the theory is provisionally corroborated. If not, it is proved false and must be either abandoned or modified to account for the inconsistency.

"Scientific theories, therefore, are accepted only provisionally. It is always possible that a theory that has withstood previous testing may eventually be disproved.").

on two factors: "(1) the reliability of the scientific principles upon which the expert testimony rests . . . and (2) the likelihood that introduction of the testimony may in some way overwhelm or mislead the jury." *Id.* at 1226. Although some of the considerations that the *Downing* court identified as relevant to an assessment of reliability are factors that the criteria proposed below would consider,[9] the thrust of our proposal is somewhat different, and in our view more reflective of scientific practices.

Our principal difficulty with the *Downing* approach is one of emphasis. Its stress on reliability suggests that a federal judge in ruling on admissibility should evaluate the *content* of the scientific evidence. The wording implies that an unscientifically trained judge will be able to determine the true state of scientific knowledge. *Id.* at 1239, n.19 (suggesting that a district court may appoint a Fed. R. Evid. 706 expert if the court has doubts that the foundational evidence "reflects the true state of scientific knowledge and opinion about it"). The *Downing* approach fails to accord sufficient deference to science to produce valuable results when a process consonant with scientific methods is employed. We suggest therefore that it is the *process* by which the theory was generated or tested that needs to be examined.

B. Rationale for Criteria Proposed and the Power of the Court

We suggest that when a court is ruling on the admissibility of expert testimony grounded in science it

[9] The *Downing* court suggested that the following eight factors might bear on scientific accuracy: (1) the degree of acceptance within the scientific community, (2) the novelty of the technique, (3) the existence of specialized literature dealing with the technique, (4) the qualifications and professional stature of the witness, (5) the non-judicial uses to which the scientific technique is put, (6) the frequency with which a technique leads to erroneous results, (7) the type of error generated by a technique, and (8) any expert testimony that has been offered in earlier cases to support or dispute the merits of a particular scientific procedure.

should determine whether scientific claims[10] have been developed within the bounds of a recognizable form of scientific inquiry. In order to make this inquiry, the court should consider the following criteria:

1. Is the claim being put forth testable?

2. Has the claim been empirically tested?

3. Has the testing been carried out according to a scientific methodology?[11]

The opinion should be rejected if the answer to any of these questions is in the negative. These questions seek to answer whether the opinion lies beyond the boundary of a recognized scientific inquiry. If it does, then the opinion cannot "assist" the trier of fact as required by Rule 702 of the Federal Rules of Evidence because it does not conform to the characteristics of "scientific

[10] We use the word "claim" rather than theory because we recognize that an expert's opinion may be admissible even in the absence of an explanatory theory. For instance, an expert could rely on an epidemiological study showing a significant association between exposure to a substance and a disease without positing a theory on precisely how the substance causes the disease to develop.

[11] We recognize that there are two additional questions that a court may have to decide:

(1) whether the theory fits established facts in the case; if it does not, it is not relevant according to Fed. R. Evid. 401. *See, e.g., Bernhardt v. Richardson-Merrell, Inc.*, 892 F.2d 440 (5th Cir. 1990) (drug exposure occurred after that point in pregnancy at which particular birth defect could have occurred); *Novak v. United States*, 865 F.2d 718, 723-24 (6th Cir. 1989) (even if epidemiological evidence supported expert's contention of an increased incidence of persons contracting a particular disease within fifteen days of a swine flu vaccination, evidence showed that decedent's symptoms commenced considerably after fifteen days).

(2) whether the expert is qualified. An expert may be unqualified because of insufficient expertise regardless of whether the scientific claim the expert wishes to put forth would meet the suggested criteria.

Since these questions do not relate to the test being proposed, we do not discuss them further.

knowledge." In other words, absent these characteristics the court should reject the opinion as not resting upon a foundation that would enable a reasonable person to draw reasonable inferences.

These questions are preliminary questions about the admissibility of evidence that must be determined by a court pursuant to Rule 104(a) of the Federal Rules of Evidence using a preponderance of the evidence standard. These questions about the characteristics of science are of a technical nature. They are the kinds of questions that historically have been allocated to a court rather than a jury. *See* John Maguire and Charles Epstein, *Preliminary Questions of Fact in Determining the Admissibility of Evidence*, 40 Harv. L. Rev. 392, 393-94 (1927) (among the reasons advanced for allocating a preliminary issue to a judge are: (1) simplifying issues for a jury; (2) improving the consistency or predictability of results; (3) sharpening issues on appeal; and (4) increasing the speed of trial).

The test we propose should lead to more efficient litigation because technical issues relating to the methodology of the study may be dispositive. Furthermore, the foundational requirement would force experts to divulge early in the litigation process the information needed to determine whether the underlying hypothesis was developed in conformity with scientific criteria. This test eases a court's task because it requires courts to make the kinds of determinations they typically make instead of asking them to evaluate the status of scientific theories or to assess their contents, questions far removed from the expertise of judges. Both the *Frye* and *Downing* tests suggest to judges that they need to comprehend complex principles of science with which they are unfamiliar and which they can ill afford the time to master.

C. The Hallmarks of a Scientific Mode of Inquiry

1. *Is the Claim Testable?*

Courts have rarely sought to identify the line of demarcation between science and non-science, although all

judges would undoubtedly refuse to admit certain evidence—such as predictions based on astrology—as capable of proving a fact in issue. Philosophers of science view science as an empirical endeavor with at least two essential characteristics. In order for a theory on which an expert relies to be deemed "scientific" (1) it must set forth a hypothesis that is capable of being proven false through observation or experiment,[12] and (2) the data produced through this testing must be capable of replication.[13] *See* Karl R. Popper, *The Logic of Scientific Discovery* 46 (1959). We suggest that this framework be employed in determining whether a particular claim is capable of affording a scientific explanation. Thus, opinions based on claims that are not capable of being tested should not be admitted into evidence.[14] Claims that are

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[12] Karl R. Popper, *The Logic of Scientific Discovery* 40-41 (1959) ("I shall not require of a scientific system that it shall be capable of being singled out, once and for all, in a positive sense; but I shall require that its logical form shall be such that it can be singled out, by means of empirical tests, in a negative sense: *it must be possible for an empirical scientific system to be refuted by experience.*") (emphasis in original); Lee Loevinger, *Standards of Proof in Science and Law*, 32 Jurimetrics J. 323, 327 (1992) ("Indeed, the distinguishing characteristic of a scientific hypothesis, as differentiated from one that is merely logical or metaphysical, is that it is capable of being falsified. An hypothesis that is tested and not falsified is corroborated, but not proved.").

[13] Panel on Scientific Responsibility and the Conduct of Research, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, Institute of Medicine, I *Responsible Science: Ensuring the Integrity of the Research Process* 59 (1992) ("In accordance with established principles of science, scientists have the responsibility to replicate and reconfirm their results as a normal part of the research process. The cycles of theoretical and methodological formulation, testing, and reevaluation, both within and between laboratories, produce an ongoing process of revision and refinement that corrects errors and strengthens the fabric of research.").

[14] *Cf. United States v. Baller*, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975) ("[T]here must be a demonstrable, objective procedure for reaching the opinion and qualified persons who can either duplicate the result or criticize the means by which

supported by data that cannot be replicated should likewise be rejected.[15]

2. *Has the Claim Been Tested?*

Even if the expert's underlying hypothesis is capable of being tested, the question remains whether the claim being asserted in the courtroom has in fact been subjected to an empirical scrutiny making it the product of a scientific inquiry.[16] Peer review in connection with a research grant or publication, or general acceptance in the scientific community as evidenced by periodical literature, should constitute presumptive proof that testing of the hypothesis has taken place.[17]

The lack of peer review or the failure of a theory or claim to have achieved a consensus in the scientific community does not, however, guarantee an absence of testing. It does mean that the court will have to look for other indicators of empirical review if the expert's opinion is challenged.

The opinion should be rejected if the theory or claim has not been tested and if proof of the theory or claim is critical to the conclusion that the expert seeks to draw.

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it was reached, drawing their own conclusions from the underlying facts.").

[15] *See, e.g., DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042, 1047-49 (D.N.J. 1992) (neither plaintiff's nor defendant's experts could replicate recalculations done by plaintiff's witness who himself could not explain how he arrived at certain numbers).

[16] *Science and Creationism*, *supra* p. 4 at 9 ("The task of systemizing and extending the understanding of the universe is advanced by eliminating disproved ideas and by formulating new tests of others until one emerges as the most probable explanation for any given observed phenomenon. This is called the scientific method.").

[17] The word "presumptive" is used because scientific misconduct sometimes occurs that is undetected by the peer review system. *See* Daryl E. Chubin & Edward J. Hackett, *Peerless Science* 125-53 (1990) (to counter the presumptive admissibility of a peer-reviewed study, the opponent would have to make a preliminary showing that such misconduct occurred); Sheila Jasanoff, *The Fifth Branch* 71-76 (1990).

For instance, an expert witness should not be allowed to conclude that substance X caused disease Y if he is relying on nothing more than a temporal association between the exposure and the injury. Without some empirical validation of the expert's hypothesis, the testimony amounts to nothing more than describing two events that are sequentially, but not necessarily causally, connected. *See, e.g., Porter v. Whitehall Lab., Inc.*, 791 F. Supp. 1335, 1344-45 (S.D. Ind. 1992); *Boyles v. American Cyanamid Co.*, 796 F. Supp. 704, 709 (E.D.N.Y. 1992) ("Each expert's methodology amounts to little more than a giant leap of faith from the alleged coincidence of the chemical exposure and [the plaintiff's] experiencing of certain symptoms. The exclusion of both experts herein is compelled by the nonexistence of any medical or scientific study which supports their conclusion.").

The lack of empirical testing may not be apparent until the evidence is challenged.[18] In a Maine case involving DNA testing, for instance, it emerged that the commercial laboratory analyzing the DNA had declared a match even though the two samples being compared had not quite matched because of bandshifting. The laboratory's experts simply corrected all of the bands in the displaced sample by a given percentage despite the lack of research showing the accuracy of such corrections.[19] *Jasanoff*, *supra* note 4 at 350-51 (discussing *Maine v. McLeod*, CR-89-62 (Cumberland County, Me., July 18, 1989)). *Cf.* NRC Report, *supra* note 19 at 76 (although the uniqueness of DNA in all persons other than identical

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[18] Part of the problem may be that the *Frye* formula, when it speaks of "the particular field in which it [the theory] belongs," obscures the possibility that empirical evidence from more than one field may be required in order to reach the conclusion that the expert wishes to state.

[19] *See also* National Research Council, *DNA Technology in Forensic Science* 61 (1992) ("NRC Report") (suggesting that because of the present inadequacy of research on the nature of bandshifting and on the various techniques that laboratories use to make corrections, samples should be declared "inconclusive" if they show bandshifting).

twins has been so firmly established that it ought to be subject to judicial notice, the DNA typing systems in use examine only a few sites of DNA variation; until further research resolves questions about the adequacy of population databases on which the frequencies of specific DNA typing patterns are based, judges should exercise caution in permiting an expert to characterize the probability of a match of two DNA samples in mathematical terms.).

3. *Has the Testing Been Carried out According to a Scientific Methodology?*

Peer review and/or recognition in the scientific community are presumptive guarantees not only that the theory was tested, but also that the testing was methodologically sound. In the absence of these factors, a court may have to rely on other factors to determine if the methodology producing the claim satisfied scientific standards. The court may, for instance, have to examine the study design,[20] data collection[21] or error rate[22] to

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[20] *See Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 423 (5th Cir. 1987) (plaintiff claimed that his depression was caused by exposure to defendant's pesticide; plaintiff's expert ignored test result that revealed high level of another chemical in plaintiff's blood that can cause depression on the ground that plaintiff had denied having contact with that chemical; appellate court affirmed district court which had granted summary judgment on the ground that evidence was excludible under Fed. R. Evid. 703).

[21] *See, e.g., DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992) (errors in entering data, relying on superseded data, and data that experts in the field would not use). The court analyzed these problems under Rule 703 of the Federal Rules of Evidence. Restructuring these problems as methodological problems means that there is no need to consider whether Rule 703 operates as an independent basis for rejecting evidence, or is only intended to operate as a hearsay exception. Compare the *per curiam* and concurring opinions in *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1114, 1118 (5th Cir. 1991) (*per curiam*), *cert. denied*, 1126 S.Ct. 1280 (1992).

[22] *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 857 (3d Cir. 1990), *cert. denied*, 111 S.Ct. 1584 (1991) (*"In re Paoli"*)

determine whether the methodology used was so skewed as to justify exclusion. The question is not whether the judge agrees with the results of the study or the scientific assumptions on which the study is based. Rather the court must decide whether the study was set up and carried out in a manner that conforms to standards in the scientific community.

These factors are interrelated; a slight modification of a well-established theory may require less in the way of scientific investigation than a brand new hypothesis. These factors do not have a quantitative threshold. We are not proposing that studies must be designed in a certain way, or contain a fixed number of subjects, in order for a court to allow an expert to state an opinion derived from these studies. We do suggest, however, that after considering these factors, and perhaps others, a court may conclude that the scientific claim being put forward has not been examined in a manner consonant with the requirements of a recognized scientific inquiry.

The main impact of this test would be two-fold: (1) judges and litigants would better understand the need to produce this information early in the litigation, and (2) judges would better understand that the limited focus of their inquiry—to determine whether appropriate testing occurred—is equivalent to other foundational inquiries they frequently make. *See, e.g., Manual for Complex Litigation*, Second, § 21.484 (providing that the admissibility of estimates obtained by sampling "will depend upon the procedures employed in selecting the sample and in obtaining information from or about the

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(there would be grounds for exclusion "if there were evidence in this record that meta-analysis is inaccurate as a mode of analysis—that the concept of combining raw data from different independent studies and re-analyzing it in total does not render accurate results."); *United States v. Smith*, 869 F.2d 348, 353-54 (7th Cir. 1989) (examination of error rates and types of errors with regard to voiceprint evidence). *See also* Michael Saks & Jonathan Koehler, *What DNA "Fingerprinting" Can Teach the Law About the Rest of Science*, 13 Cardozo L. Rev. 361, 368 (1991).

sample. The proponent of such evidence has the burden of establishing conformity with generally recognized statistical standards, a task that will ordinarily involve expert testimony."); *Pittsburgh Press Club v. United States*, 579 F.2d 751 (3d Cir. 1978) (setting out criteria for sampling).

Ascertaining if an appropriate scientific methodology was used in testing a theory does not require the court to undertake the far more difficult task of comprehending and assessing the substance of the theory. Furthermore, although the dissonance between "general acceptance" and the provisional nature of scientific claims makes "general acceptance" an inapt guide for the admissibility of evidence, general agreement on the methodological standards for a particular discipline is feasible. *See, e.g.*, Technical Working Group on DNA Analysis Methods, *Guidelines for a quality assurance program for DNA restriction fragment length polymorphism analysis*, Crime Lab Dig. 16 (2): 40-95 (1989) (guidelines developed by the FBI, the Royal Canadian Police, state forensic laboratories and commercial laboratories to deal with issues such as documentation, validation of procedures, proficiency testing, handling and labeling of samples and laboratory contamination); Devra L. Davis, Barbara Mandula and John Van Ryzubm, *Assessing the Power and Quality of Epidemiologic Studies of Asbestos-Exposed Populations*, 1 Toxicology & Indus. Health 93 (1985) (reporting on Ontario Royal Commission report and a National Research Council report, both of which evaluated asbestos studies in terms of methodologic factors) (epidemiological studies); Association of the Bar of the City of New York, *Recommendations on Pretrial Proceedings in Cases with Voluminous Data, reprinted in The Evolving Role of Statistical Assessments in the Courts* 245-54 (Fienberg ed. 1988) (standards for statistical experts).

Furthermore, the court may be able to get neutral assistance to deal with this issue. Under the *Frye* test or the *Downing* test, courts may be loath to turn to a

court-appointed expert because any expert who knows enough to comment on the particular claim's position in the scientific community, or its reliability, may well be so closely involved with the controverted substantive theory that the court fears bias. Finding an expert to advise the court about methodology is considerably easier; persons who have no special knowledge about the particular controverted substantive issue can be knowledgeable about a field's methodological requirements. *See Renaud v. Martin Marietta Corp.*, 749 F. Supp. 1545, 1552 (D. Colo. 1990), *aff'd*, 972 F.2d 304, 307-08 (10th Cir. 1992) (court granted summary judgment for defendants in case alleging that plaintiffs' cancers and birth injuries were caused by toxic wastes dumped in water after court-appointed geologist advised court that it was an "unsound scientific practice" to base all conclusions about the continuous release of contaminants over an 11-year period on one sample of water).

D. The Operation of the Proposed Test: Foundational and Procedural Requirements

According to the test proposed, the foundational information needed to determine if the theory had been tested in accordance with scientific methods would have to be disclosed in the expert's report during discovery [23]

[23] Although the current Federal Rules of Civil Procedure do not require disclosure of experts' reports, or authorize depositions absent court order, in practice, parties frequently stipulate to exchange experts' reports and to depose all experts. Day, *Expert Discovery in the Eighth Circuit: An Empirical Study*, 122 F.R.D. 35, 50, 57 (1988) (88% of attorneys responding reported depositions by stipulation and exchange of information). Under proposed amendments to the Rules of Civil Procedure, these provisions would become mandatory. *See* Standing Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, *Proposed Amendments to the Federal Rules of Civil Procedure* (Sept. 1992) (requires mandatory disclosure from experts of "a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinion; any exhibits to be used as a summary of or support for the opinions . . .").

or at the final pretrial conference.[24] If prior to trial a party failed to show that an expert listed as a trial witness had relied on a properly tested theory, then the opponent could move *in limine* to exclude that expert's testimony.[25]

A court need not conduct a hearing unless (1) the movant adequately showed that it cannot be ascertained from the reports whether the expert's theory was tested, or tested appropriately, and (2) the expert failed to supply the missing information. A refusal to produce needed foundational material should lead to preclusion of the expert. In cases where there is a genuine dispute about adequate testing, the court may need to hold a hearing.

Although hearings obviously consume scarce judicial time, they may in the long run lead to shorter and less expensive proceedings. They would avoid results such as the enormous investment of appellate time in *Christophersen v. Allied Signal Corp.*, 902 F.2d 362 (5th Cir. 1990), *rev'd en banc*, 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 112 S.Ct. 1280 (1992),[26] in which the central

[24] A court has adequate power to require experts to produce reports in connection with the final pretrial conference. *See* Fed. R. Civ. Pro. 16(c)(11) (providing that the court may take action regarding "such other matters as may aid in the disposition of the action") and (d) (providing that at a final pretrial conference, the participants "shall formulate a plan for trial, including a program for facilitating the admission of evidence.").

[25] This requirement is not inconsistent with Fed. R. Evid. 705 which provides that an expert may *testify* "without prior disclosure of the underlying facts or data." Rule 705 is a rule that applies at trial only; it has no bearing on threshold requirements that have to be satisfied before the expert will be allowed to testify.

[26] In *Christophersen*, affidavit of the plaintiff's expert stated that decedent's death from a rare form of colon cancer was due to exposure to nickel and cadmium fumes at his place of work; expert conceded the absence of epidemiological, animal or in vitro studies investigating this association, but stated that nickel and cadmium had been implicated in small-cell carcinoma of the lungs, that the cells in decedent's colon cancer were likewise small, and that "[b]ased on what's known about the biochemical nature of small-cell" carcinoma, one could conclude that small-cell carcinoma throughout the body had a similar pathogenesis. *Christophersen* at 1115. The affidavit of the defendant's expert alleged that "[t]hese tumors in fact have to my knowledge never have been shown to have a common causation or share a proven common origin." 902 F.2d 362, 366 (5th Cir. 1990). The district court granted summary judgment for defendant on the basis of these affidavits without conducting a hearing. The four defense affiants were never deposed. 939 F.2d at 1122.

dispute, according to the test proposed by *amicus*—has plaintiff's expert's claim been empirically tested or is it merely a hunch?—was never explored in a procedural posture that allowed the development of an adequate record.[27]

II. WHEN RULING ON THE SUFFICIENCY OF SCIENTIFIC EVIDENCE, A COURT MUST EVALUATE THE EVIDENCE IN LIGHT OF A LEGAL STANDARD OF PROOF.

A. The Legal Standard for Sufficiency

When a defendant challenges scientific evidence as insufficient, whether before trial, at trial, or after trial, the question for the court remains the same. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52 (1986). May the court conclude as a matter of law that the evidence "is so one-sided that one party must prevail?" *Id.* at 251-52. If the answer is yes, then the court must dismiss the case without submission to the jury. Questions of sufficiency will arise when the defendant claims that the scientific evidence underlying plaintiff's claim is such that no reasonable juror could find for the plaintiff.

[27] *In re Paoli, supra* note 22 at 855 (reversing grant of summary judgment on affidavits; "At least some process should have been devised to afford plaintiffs a surrogate for that trial scenario where the equivalent evidentiary exclusion and adverse judgment might occur.").

B. Relating the Legal Standard to Scientific Proof

Ordinarily, if plaintiff and defendant have presented conflicting hypotheses that are the product of an appropriate scientific inquiry, the jury will have to resolve the controverted issues. If the defendant challenges the sufficiency of the plaintiff's evidence, however, the court will first have to decide whether an issue for the jury exists.

Whether evidence is sufficient is a matter of law, not science. In scientific hypothesis testing, the hypothesis being investigated (the "alternative" hypothesis) is accepted only if the data obtained would be quite unlikely to result if the alternative hypothesis were not true. When scientists reject the "null" hypothesis,[28] they are not making a statement of an established "truth."[29] They are making a probabilistic statement given the present state of knowledge. Determining the legal consequences that flow from this imperfect state of knowledge lies beyond the domain of science.[30]

It is a court that must decide whether the degree of scientific uncertainty is such that the plaintiff has failed to introduce sufficient probative evidence to meet its bur-

[28] The state of events in the absence of the alternative hypothesis is usually referred to as the "null" hypothesis.

[29] *Cf.* Office of Science and Technology Policy (OSTP), *Chemical Carcinogens: A Review of the Science and Its Associated Principles*, 50 Fed. Register 10371-10442 (1985) (Principle 19: "A high-quality negative epidemiological study, while useful, cannot prove the absence of an association between chemical exposure and human cancer.").

[30] Institute for Health Policy Analysis of Georgetown Medical Center, *Conference on Causation and Financial Compensation* 18 (1986) ("A conscientious scientist will weigh the available data and reach an assessment of its strength, but science cannot tell the scientists at what point the data are strong enough to warrant an award of compensation. One may or may not agree with the legal concepts and may propose alternatives, but one cannot look to science for an absolute *decisionmaking* standard because none exists.") (emphasis in original).

den of proof.[31] When the plaintiff is seeking compensation for injuries allegedly suffered because of exposure to a toxic substance, for instance, it is the judge and not a scientist who must bear ultimate responsibility for determining whether the scientific evidence satisfies the legal standard of proof. In ruling on sufficiency, the court, therefore, properly evaluates the present state of available scientific knowledge. Since determinations about the sufficiency of scientific evidence entail policy concerns, the court will also have to consider the underlying objectives of science and the law in order to ascertain the extent to which scientists' conclusions have relevance for the legal system. An example of the kind of question courts must answer is discussed below.

Animal Studies and Epidemiological Evidence. Studies showing that a particular substance may cause harm in animals are routinely used in risk assessment. Ordinarily, the goal of risk assessment is not to prove causation, but rather to characterize the nature and possibility of harm and its consequences. When animal studies are introduced in litigation by plaintiffs to prove causation, two assumptions must be made in order for the evidence to be probative: (1) that if the substance was toxic in animals it would also be toxic in humans; and (2) that extrapolation is possible from the higher and more intense level used in the study to the lower level at which the plaintiff was actually exposed.

If a plaintiff relies solely on animal studies, how should a court rule on sufficiency? Can it say that jurors may not be permitted to decide such a case because the extrapolations required to make these studies relevant to humans mean that they are insufficient to prove causa-

[31] Lee Loevinger, *On Logic and Sociology*, 32 Jurimetrics J. 527, 530 (1992) ("there is no logically rigorous definition of what a statement of probability means with reference to an individual instance").

tion?[32] Or should the court allow the case to go to the jury since a high correlation does in general exist with regard to human and animal reactions? Or should the court approach the problem by focusing on the particular animal study in question and determining whether it has a statistical significance and biologic plausibility sufficient to satisfy the plaintiff's burden of proof.[33]

Although the court's analysis will be informed by the available science, the judge's decision whether this available evidence is "so one-sided" that plaintiff must lose is ultimately a policy issue that an appellate court may have to resolve. Whether a plaintiff should be precluded by a judge from receiving compensation if such evidence is all that is available, or whether plaintiffs should be given the opportunity of having a jury decide the causation issue is in part determined by judicial views on the social policies underlying products liability law.

Most of the decided cases involving animal studies have, however, arisen in a different context. The question has not been whether plaintiff has made a prima facie case solely on the basis of animal studies, but rather whether plaintiff's animal study evidence is sufficient when the defendant's epidemiological proof does not show

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[32] *Cf. In re Paoli, supra* note 22 at 853 n.27 (suggesting that the trial court "may have meant to exclude the animal studies as irrelevant under Rule 402 because, even if they showed correlation between PCBs and animal disease, they were not probative of a connection between PCB exposure and human disease.").

[33] *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1359 (6th Cir. 1992) (The court left open the possibility that "there may be other animal experiments which . . . because of the extreme toxicity of the substance tested, would permit a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans."). Because animal studies are routinely used in the risk assessment of foods, drugs, and other substances it is theoretically possible, but unlikely, that such extreme toxicity will arise in connection with a tort claim.

any effect on humans.[34] In resolving these cases on sufficiency grounds, many courts have nevertheless cited evidentiary rules dealing with admissibility.[35] We suggest that the Federal Rules of Evidence do not apply at this point in the analysis. The court must decide whether the availability of epidemiological proof relating to humans leads to the conclusion that the contrary studies about animals' reactions have been shown not to be probative.[36] If the court so decides, and consequently finds that plaintiffs have failed to meet their burden of proof, it is creating a rule of law. It is saying that once sufficient epidemiological evidence exists a plaintiff may no longer reach the jury solely on the basis of animal studies.[37]

III. A THEORY UNDERLYING AN EXPERT'S OPINION NEED NOT HAVE BEEN SUBJECTED TO PEER REVIEW IN ORDER TO BE ADMISSIBLE.

The Ninth Circuit's opinion below strongly suggests that scientific studies prepared in anticipation of litigation must be rejected if they have not been subject to peer review. *Daubert v. Merrell Dow Pharmaceuticals,*

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[34] *See, e.g., Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 313-14, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990) ("Brock v. Merrell Dow"); *In re Agent Orange Product Liability Litigation*, 611 F. Supp. 1267, 1273 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

[35] *See, e.g., Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (case arose in procedural posture of a judgment n.o.v. granted by the trial court, but the court seems to be relying on Fed. R. Evid. 703).

[36] The likelihood that an epidemiological study would show the defect in question will have to be considered.

[37] *See, e.g., Brock v. Merrell Dow, supra* note 34 at 312. But "sufficient" does not mean a single negative epidemiological study. In fact, epidemiology offers standardized expressions of the size of effect that might be present yet not be detected in a study of a particular size or power.

Inc., 951 F.2d 1128, 1131 (9th Cir. 1991), *cert. granted*, 61 U.S.L.W. 3284 (1992). Although we agree that when a study has been peer-reviewed, it has presumptively been conducted in accordance with the dictates of scientific methodology, we do not think that an absence of peer review proves that the study lacks these characteristics.[38]

A. Peer Review as a Sole Condition Is Incompatible with the Realities of Litigation.

A requirement that all studies must be peer-reviewed before they can be relied upon by an expert witness presupposes a view of litigation and science at odds with reality. It assumes that scientific answers exist that are waiting to be summoned when a legal issue appears that hinges on scientific proof. In actuality, recent developments in both the criminal [39] and civil [40] spheres indicate quite clearly that often the studies that become relevant in determining a legal issue are initiated in reaction to the litigation process.

Insisting that parties' responses to this ongoing process be limited to studies that have been peer-reviewed is

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[38] Other courts have declined to exclude expert testimony solely because it relies on studies that have not been subjected to peer review. *See In re Paoli*, *supra* n.22; *Brock v. Merrell Dow*, *supra* note 34 at 313.

[39] A comparison of a 1990 article on DNA testing, Janet Hoeffel, *The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant*, 42 Stan. L. Rev. 465 (1990) (raises numerous as yet uninvestigated and unresolved issues) with the NRC Report, *supra* note 19 indicates how scientific research evolved, and is continuing to evolve, in reaction to forensic pressures.

[40] *See* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hast. L.J. 301, 331-48 (1992) (examines Bendectin research over the life cycle of the Bendectin litigation and concludes that "[t]here was a substantial mobilization of resources devoted to the study of Bendectin, much of it apparently in response to the litigation and concomitant political pressure." *Id.* at 347.).

unresponsive to the constraints imposed by litigation. How can lawyers prepare if the competence of their experts to testify is contingent, not on the scientific nature of their work, but on whether it will have been accepted for publication by the time a motion for summary judgment is made? Suppose the editorial review of the paper is in the process of negotiation—must the legal process halt? [41]

B. Peer Review as a Sole Condition Is Incompatible with the Role of Science in Litigation.

Peer review is not an objective, universally accepted set of procedures but rather a process that reflects the social processes and social conflicts that underlie scientific claims. The peer review process operates in part to clarify and to improve work presented for publication, and in part to make particular scientific research communities relatively immune to criticism from outsiders. Consequently, a person who is advocating a view at odds with the currently received wisdom may encounter difficulties in having his or her work published.

The real purpose of peer review, however, is not getting the article into the journal, but the *fact* of its publication—which makes the claims accessible to the skepticism of the larger scientific community. This important and constructive gatekeeping function of peer review is the reason we endorse its use as a factor indicating proper scientific practices.

The entanglement of peer review with the adversarial process, however, remains a challenge. If peer review is not mandatory, a lawyer's natural inclination will be to

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[41] *See* Daryl E. Chubin & Edward J. Hackett, *Peerless Science* 88 (1990) ("Today peer review has the character of an extended trilateral negotiation among authors, editors, and reviewers. Papers are rarely accepted at first sight, but instead undergo at least one and not uncommonly as many as five rounds of revision and publication.").

advise any scientist hired as an expert not to submit for publication work commissioned in anticipation of litigation. The lawyer will be afraid that any rejection, modification, inquiry or criticism by a journal or reader will be used by an opponent in litigation to discredit the work. Were peer review to become mandatory, on the other hand, lawyers might well advise retained experts to submit manuscripts to journals having the least restrictive requirements in order to minimize feedback that may be misinterpreted by a jury. Courts are unlikely to permit extensive explorations about the relative standing of different publications in the midst of already complicated trials. *See* Fed. R. Evid. 403. Making peer review a condition, however, may ultimately be self-defeating in terms of the objective sought—improving the quality of the scientific claims urged in litigation.

For these reasons as well as the practical concerns noted earlier, submission to peer review should be regarded as a favorable attribute, but the lack of peer review should not be treated as a conclusive factor mandating exclusion of an expert.

CONCLUSION

In this brief, *amicus* has explored the various postures in which courts must deal with issues posed by the introduction of scientific evidence into the courtroom. Our objective has been to delineate more precisely when law should defer to science, and when science must give way to the law. The tests that judges currently use in ruling on the admissibility of expert proof grounded in science are not adequately geared to the nature of the scientific enterprise. We propose a new set of criteria that would enable the product of a recognized form of scientific inquiry to be utilized more effectively in decision making in the federal courts.

For the foregoing reasons, the Court should clarify the standard to be used in determining the admissibility of scientific evidence.

Respectfully submitted,

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APPENDIX

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[1] The views of the members of the Carnegie Commission on Science, Technology, and Government reflected herein are personal views, are not made in their professional capacities and do not reflect the views of their affiliates.